

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, VISN 8, West Palm Beach VA Medical Center. 548-12-3-440-0077

2. Nature and/or Description of the Action Being Processed: New contract for the one time purchase of a Trabectome for use in glaucoma surgeries. Trabectome® is a revolutionary procedure for the treatment of glaucoma that is being used around the nation by Government Facilities, Hospitals, and ASC locations. The unique characteristic that differentiates Trabectome® from other glaucoma technologies is that it is the only FDA allowed surgical product for glaucoma that opens trabecular meshwork using an ab-interno surgical approach. NeoMedix's intellectual property position makes it unlikely that competitive products will be offered through other sources.

Trabectome® (registered trademark by NeoMedix Corporation) is a proprietary device and surgical approach for treating glaucoma in adults and children (FDA – 510(k)). It is protected by multiple patents licensed worldwide and solely by NeoMedix Corporation or owned by NeoMedix Corporation.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Non-Disposable

Trabectome System 600026	\$39,775
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Includes:

- 1- I/A Console
- 1- RF Generator
- 1- Roller Stand with Tray
- 1- Footswitch
- 1- Activation Cable
- 1- Power Cord
- 1- AC Adapter

Trabectome Goniolens 600009	"L"	\$500
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Trabectome Goniolens 600010	"R"	\$500
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Disposable

Procedure Pack Plus (600018) includes; Disposable Handpiece, I/A Fluidics, Tray Drape, Keratome, IFU, Ocucoat, I/A Cannula Estimated annual cost \$685 X 12= \$ 8220

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;

- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

a. Only One Responsible Source (FAR 6.302-1) – New contract for the one time purchase of a Trabectome for use in glaucoma surgeries. Trabectome® is a revolutionary procedure for the treatment of glaucoma that is being used around the nation by Government Facilities, Hospitals, and ASC locations. The unique characteristic that differentiates Trabectome® from other glaucoma technologies is that it is the only FDA allowed surgical product for glaucoma that opens trabecular meshwork using an ab-interno surgical approach. NeoMedix's intellectual property position makes it unlikely that competitive products will be offered through other sources.

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6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: This is a new patent, protected piece of medical equipment. No other source currently exists that can be used to perform this glaucoma procedure.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: We will determine that the price is fair and reasonable prior to award..

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: The part-time Ophthalmologist that works both at the VA and at Bascom Palms had been fellowship trained in Glaucoma surgery and has attended trade shows, read journal articles and teaches the Ophthalmology fellows in Glaucoma surgery. This is the only item on the market that will meet the strict requirements for safe glaucoma surgery.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: None

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: No other vendors in market.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: The government will seek competition in future requirements if more services become available.

12. Requirements Certification :

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Name: Jane Lipinski


Date:


Title: Program Specialist-Surgery, COR

Facility: 548-West Palm Beach VA

13. Approvals in accordance with FAR 6.304

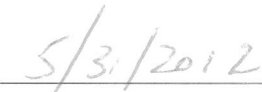
- a. **Contracting Officer's Certification:** (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name
Contracting Officer
Facility


Date

- b. **Product Line Supervisor (PLS):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name
Contracting Supervisor
Facility


Date

- c. **DNCM/NCM:** (SAT to \$500,000) I certify the justification meets requirements for other than full and open competition.


Mitchell Thomas
Network Contract Manager
VISN 8

Date

- d. **SAO:** I certify the justification meets requirements for other than full and open competition.

N/A

David M. Fitzgerald
Director
Service Area Office, East

Date

- e. **VHA HCA Review and Approval:** (over \$500,000) I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

N/A

HCA
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

- f. **VA Deputy Senior Procurement Executive Approval (over \$10 not exceeding \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

N/A

Iris B. Cooper
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- g. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

N/A

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date